



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/347,311 07/02/99 PLAETINCK

G B0192/7010

EXAMINER

HM22/0328

SHUKLA, R

JOHN R VAN AMSTERDAM
C/O WOLF GREENFIELD & SACKS P C
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON MA 02210-2211

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/347,311

Applicant(s)

PLAETINCK ET AL.

Examiner

Ram Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24,38-48 and 68-70 is/are pending in the application.
- 4a) Of the above claim(s) 25-37,49-67 and 71-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-24,38-48 and 68-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of the invention of group I, claims 1-24, 38-48, and 68-70 in Paper No. 9 is acknowledged.
2. Claims 25-37, 49-67, and 71-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.
3. It is noted that upon further consideration and art search, it was realized that the invention of group I (claims 1-24, 38-48, and 68-70) contains three distinct inventions termed groups IA, IB, and IC. Applicants are requested to elect an invention from the groups IA-IC.

It is noted that Groups II-X presented in the previous office action and the reasons as to why the inventions were distinct have also been restated.

- IA. Claims 1-18, 20-22, and 38-46, drawn to method of identifying genes by producing a dsRNA in a microorganism, classified in class 435, subclass 7.35.
- IB. Claims 1-15, 17-21, 23, 24, 38-45, and 47-48, drawn to method of identifying genes by producing a dsRNA in an animal, classified in class 800, subclass 3.
- IC. Claims 68-70, drawn to an expression vector for expressing a transcription factor, classified in class 435, subclass 320.1.
- II. Claims 25-37, drawn to a method of making a transgenic organism by altering the expression of gene, using a dsRNA, classified in class 800, subclass 21.
- III. Claims 49, 71 and 72, drawn to a plasmid pGN1 and an organism transformed with said plasmid, classified in class 800, subclass 21.
- IV. Claim 50, drawn to a plasmid pGN100, classified in class 435, subclass 320.1.
- V. Claims 54-59, drawn to a method of alleviating plant infestation by a pest, classified in class 800, subclass 278.
- VI. Claims 51, 60-62 and 91, drawn to a yeast two hybrid plasmid and an expression vector, classified in class 435, subclass 320.1.
- VII. Claims 52, 60-67 and 79-83, drawn to a plasmid, an expression vector and a method of identifying cellular transformation using said plasmid and expression vector, classified in class 435, subclass 320.1.

Art Unit: 1632

- VIII. Claims 53, 60-67, and 79-83, drawn to a plasmid, an expression vector and a method of identifying cellular transformation using said plasmid and expression vector, classified in class 435, subclass 320.1.
 - IX. Claims 73-78 and 84, drawn to a method of introducing a DNA in an organism by feeding said organism a microorganism, classified in class 435, subclass 455.
 - X. Claims 85-90, drawn to a method of assigning function to a DNA sequence in a multicellular organisms by producing dsRNA in said multicellular organism, classified in class 800, subclass 3.
4. Claims 60-62 are generic to inventions of groups VI-VIII. Should any of these groups be elected, claims 60-62 will be examined to the extent they encompass the elected invention.
5. Claims 63-67 and 79-83 are generic to inventions of groups VII and VIII. Should any of these groups be elected, claims 63-67 and 79-83 will be examined to the extent they encompass the elected invention.
6. Claims 1-15, 17, 18, 20, 21, and 38-45 encompass subject matter common to both groups IA and IB. Should any of these groups be elected, claims 1-15, 17, 18, 20, 21, and 38-45 will be examined to the extent they read on the elected invention.
7. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:
- The invention of group I A and IB are related to each other because both the methods are based on the principle of identifying genes by dsRNA inhibition of gene function, however, the methods of the groups I A and IB are distinct from each other because they are carried out in a prokaryotic cell and an eukaryotic multicellular organism (a nematode), respectively. It is noted that the vector that would function in a bacterium (method of group IA) will not be functional in the method of group IB because the mechanism of transcription and transcriptional regulation in a bacterium and an eukaryotic animal are different for the two methods (of the groups IA and IB). Furthermore, method of screening, organism culture, as well as methods of isolating DNA will also be different. Therefore, the inventions of the groups IA and IB will require separate searches in the patent and non-patent literature.

Inventions of the groups IA and IB are related to the invention of the group IC as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the invention of group recites an expression vector that expresses a transcription factor for use in the methods of the groups IA and IB. However, it is noted that an expression vector that would function in the method of IA will not function in the method of group IB because the structure of promoter, transcription factors and other determinants of transcription in a bacterial cell are different from those of an eukaryotic cell or multicellular organism, such as a nematode. In addition to this, the subcombination has separate utility such as: in methods for producing a recombinant protein in vitro in a cell culture system, or for transcribing RNA in vitro. Therefore, the inventions of the groups IA, IB and IC are patentably distinct each from the other and will require separate searches in the non-patent literature.

8. The inventions of the groups I, II, V, IX, and X are drawn to different methods comprising different steps and therefore are patentably distinct each from the other. For example, the inventions of both, groups I and X are drawn to methods of identifying DNA sequences that confer a certain phenotype to a cell or a multicellular organism respectively, however, they are patentably distinct because the invention of group I is drawn to the method carried out in a cell whereas the method of group X is carried out in a multicellular organism, and therefore, the steps of these methods would be different, for example, introduction of the DNA, mechanism of expression, site of expression etc. The invention of the group II is patentable distinct from that of groups I and X, because the method of group II is to make a transgenic animal, steps of which are different from those of the groups I and X, for example, the method of group II would require introduction of a transgene into the germ cells of an animal and all the cells of the transgenic animal would comprise the transgene. The invention of group V is drawn to a method of decreasing plant infestation by a pest and therefore its steps would be different from those of the method of groups I, X and II and furthermore, the vector used for introducing the DNA into the plant would have different sequence elements, such as promoter structure. The invention of

Art Unit: 1632

group IX is drawn to a method of introducing DNA in an organism by feeding it a microorganism and therefore, is different from those of the inventions of the methods of groups I, II, V, and X because none of these methods involve introduction of DNA by feeding a microorganism. Accordingly, the inventions of the groups I, II, V, IX and X will require separate searches, for example, in the non-patent literature.

The inventions of the groups III, IV, VI, VII, and VIII are drawn to different plasmids and are patentably distinct each from the other because they have different sequence structure and have different structural components. For example, the plasmids of groups III, IV, and VI have different sequence structures, disclosed in Seq ID No 1, 2, and 3-11. Furthermore, they also have different structural elements, such as promoters, selectable marker genes etc. Therefore the inventions of groups III, IV, VI, VII, and VIII will require separate searches, for example, in the non-patent literature and in the sequence database.

The inventions of the groups III, IV, VI, VII, and VIII are also patentably different each from the inventions of the groups I, II, V, IX and X because they are drawn to plasmids and expression vectors while the inventions of groups I, II, V, IX and X are drawn to different methods. While the methods of the groups I, II, V, IX and X can not be used for making the inventions of the groups III, IV, VI, VII, and VIII, the inventions of the groups III, IV, VI, VII, and VIII can be used for multiple purposes. In conclusion, the inventions of the groups I-X are patentably distinct each from the other and they would require separate searches, for example, in the non-patent literature.

9. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Art Unit: 1632

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instruction, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.

Ram R. Shukla, Ph.D.


KAREN M. HAUDA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600